



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,449	11/30/2001	Shamim M. Malik	050623.00134	3441

45159 7590 04/04/2011
SQUIRE, SANDERS & DEMPSEY (US) LLP
275 BATTERY STREET, SUITE 2600
SAN FRANCISCO, CA 94111-3356

EXAMINER

TYSON, MELANIE RUANO

ART UNIT	PAPER NUMBER
----------	--------------

3773

MAIL DATE	DELIVERY MODE
-----------	---------------

04/04/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/997,449	Applicant(s) MALIK ET AL.	
	Examiner MELANIE TYSON	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-6,8-10,13 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/28/11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to the applicant's amendment received 28 January 2011. The application is not in condition for allowance for the reasons set forth below. Claims 2, 3, 7, 11, 12, and 14-30 remain cancelled.

Response to Arguments

The applicant's arguments with respect to the combination of Taylor and Ecer have been fully considered but they are not persuasive. The applicant argues that one would not look to Ecer to modify Taylor's stent (i.e., non-analogous art). However, Ecer suggests that carbon is a known material for increasing the hardness of steel (for example, see column 1, lines 14-18). Stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stainless steel stent body with a carbon deposit as taught by Ecer in order to provide the stent with these advantages. The applicant also argues that method of implanting carbon near the surface of the stent as taught by Ecer would not result in a change in properties in the vast majority of the stent, and since no significant improvement in tensile strength, stiffness, and resistance to radial compression of the stent would be observed, one would not look to Ecer to modify Taylor (as described in an affidavit submitted). However, since at least a local increase in hardness is achieved, it is the examiner's position one having ordinary skill in the art would look to Ecer to modify Taylor to achieve such improvements throughout

Art Unit: 3773

the stent. In response to the applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned from the applicant's disclosure, such a reconstruction is proper. The applicant has not provided any arguments directed to the Narayanan reference and thus the combination of Taylor and Ecer with Narayanan is still deemed proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-6, 8-10, 13, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (U.S. Patent No. 6,083,257 - cited on 892 dated

6/6/08), Ecer et al. (U.S. Patent No. 4,486,247 - cited on 892 dated 6/6/08), and Narayanan et al. (U.S. Patent No. 5,336,518-cited on 892 dated 6/23/09).

Taylor discloses a stent (see entire document) comprising a radially expandable metallic stent body formed of a stainless steel alloy (for example, see column 5, lines 51-56 and lines 62- 63) having a polymer film in intimate contact with the tissue contacting surface of the stent (for example see column 3, lines 63-67). Taylor fails to disclose the stent body comprises a carbon deposit.

Ecer discloses a stainless steel base material being modified by having carbon implanted within the surface of the stainless steel base material at a depth from about 300 to about 2500 angstroms, or of about 300 to about 1000 angstroms below the steel surface, which falls within the claimed range (for example, see column 1, lines 50-54 and 60-64). Ecer suggests that carbon is a known material for increasing the hardness of steel (for example, see column 1, lines 14-18). It is well known in the art that stainless steels having improved hardness yield stents having increased tensile strength, stiffness, and resistance to radial compression, thus improving the performance of the stent within, for example, a pulsating lumen. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's stainless steel stent body with a carbon deposit as taught by Ecer in order to provide the stent with the advantages described above. Taylor as modified by Ecer fails to disclose the polymer film layer comprises an acrylate and is chemically bonded to the carbon deposit.

Narayanan discloses a metallic stent comprising a polymer film (see entire document). Narayanan teaches polymer films containing acrylate, such as HFBMA, enhance metallic surfaces with permanent improved biocompatibility. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Taylor's device, as modified by Ecer, with a polymer film containing acrylate as taught by Narayanan. Doing so would improve the biocompatibility of the device. Narayanan further teaches the film is applied to the metallic surface via plasma polymerization deposition. The applicant discloses in the specification that depositing films to stents via plasma polymerization deposition is well known in the art, wherein "one having ordinary skill in the art will recognize that some fragmentation of the acrylate typically occurs during the plasma polymerization deposition of the film layer, resulting in an acrylate-like polymer layer of fragmented acrylate, which will be covalently bonded to carbon deposits." Therefore, by the applicant's own admission, applying Narayanan's acrylate containing polymer film via Narayanan's technique of plasma polymerization deposition to Taylor's device as modified by Ecer would yield a device in which the polymer film layer is covalently bonded to the carbon deposit as recited in the claims.

For examination purposes, claim 5 is being treated as a product by process limitation, in that "the plasma-polymerized polymer film is formed by exposing the stent to an acrylic acid plasma" refers to the process of forming the plasma-polymerized polymer film and not to the final product created. As set forth in MPEP 2113, "Even though product-by-process claims are limited by and defined by the process,

Art Unit: 3773

determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product in the prior art, the claim is unpatentable even though the prior product was made by a different process.” In re Thorpe, 777 F.2d 695,698,227 USPQ 964,966 (Fed. Cir. 1985). Examiner has evaluated the product claim without giving much weight to the method of its manufacture. Therefore, in this case, a plasma-polymerized polymer film formed by exposing the stent to an acrylic plasma is directed to the method of making the polymer film and not to the final product made. It appears that the product disclosed by Taylor as modified by Ecer and Narayanan would be the same, especially since both applicant’s product and the prior art product have the same final structure of a metallic stent having a plasma-polymerized polymer film layer chemically bonded thereto.

With further respect to claim 6, Narayanan discloses the activated acrylate may comprise functional groups such as carboxylate or amine (for example, see column 3, line 43 and 62-63).

With further respect to claim 10, Narayanan also teaches bioactive agents formed on the plasma polymerized polymer film (for example, see column 3, lines 44-56). It would have been obvious to one having ordinary skill in the art at the time the invention was made to form a therapeutic substance on the modified film layer above as taught by Narayanan in order to enhance treatment and promote healing at the treatment site.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE TYSON whose telephone number is (571)272-9062 and e-mail address is Melanie.tyson@uspto.gov. The examiner can normally be reached on Monday through Thursday 8-7 (IFP).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 3773

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie Tyson/
Primary Examiner, Art Unit 3773
March 28, 2011